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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,662	01/11/2002	Andreas Jordan	1214.00026	9966

7590 12/19/2006  
Wood Phillips Van Santen Clark & Mortimer  
500 West Madison Street Suite 3800  
Chicago, IL 60661

EXAMINER
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CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/914,662	<b>Applicant(s)</b> JORDAN, ANDREAS	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-3, 6, 7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### DETAILED ACTION

Claims 1 and 3 have been amended. Claims 8 and 17 have been canceled. Claims 1-3, 6, 7, and 9-16 are pending. Claims 9-16, remain withdrawn from consideration. Claims 1-3, 6 and 7 are under consideration.

Sections of Title 35, U.S. code, not found in this action can be found in a previous action.

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record set forth for the rejection of claim 8 in the previous Office action. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 1 requires that the method of claim 1 be carried out with the culture medium as set forth previously in claim 8. Claim 1 encompasses all types of cancer cells residing in solid tissues which can be separated by mechanical fragmentation. This includes all adenocarcinomas, carcinomas, sarcomas, melanomas and gliomas and other nervous system tissues. It is noted that culture conditions for each tumor cell type requires optimization. Each ingredient in claim 1 is specified as a range of weight per volume amounts. Claim 1 requires 7 inorganic salts, 21 amino acids, 19 vitamins and 6 other ingredients, all of which require optimization to a value within the specified range. It is noted that out of the "classic media" formulations, such as RPMI, MEM, DMEM, F-12K, DMEM-F12, L-15, McCoy's 5A, Iscove's Modified Dulbecco's and Hybri-Care, only RPMI requires  $\text{Ca}(\text{NO}_3)_2$ , and none require both  $\text{Ca}(\text{NO}_3)_2$  and  $\text{CaCl}_2$ .

Primary tumors are a mixture of tumor cells, corresponding normal cells, stromal cells and immune cells (Freshney, Culture of Animal Cells, 1994, page 350-351, see page 351, first

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paragraph under “Characterization”). The art teaches that tumor cells taken from patients, in addition to requiring the optimization of culture conditions to support the selected cell type, require conditions to prevent the “overgrowth” of connective tissues and vascular cells which predominate conventional culture systems (ibid, see page 350, bridging paragraph between columns 1 and 2). The art teaches the necessity of providing selective conditions which replace any of the growth factors provided by the stoma in vivo (ibid, see page 351, especially column 1, last two sentences). It would be undue experimentation to one of skill in the art to practice the invention of claim 1 with the recited medium composition for every type of cancerous tissue encompassed by claim 1 because each of the ingredients of claim 1 require optimization to support each tumor type and suppress the overgrowth of contaminating connective tissues and vascular cells, and none of the ingredients are specified without a range. Claim 1 reads on tumor biopsy specimens taken from patients. Thus, one of skill in the art would be restricted in the type of material used for the optimization, because it is well known that tumor cell lines have different requirements for viability than tumor explants or biopsy samples. Thus, one of skill in the art would not have unlimited amounts of tissue to commit to optimization studies. Given the breadth of both of claims 1 and 8, and the lack of specific teachings in the specification which would serve to direct one of skill in the art to particular set values of the different ingredients of claim 1 to a particular tumor type, such as breast adenocarcinoma or melanoma, one of skill in the art would be subject to undue experimentation in order to carry out the instant methods requiring the broadly claimed medium.

Applicant argues that the counter ions present in the instant formulation make no difference to the end product, stating that when in solution the culture medium does not have  $\text{Ca}(\text{NO}_3)_2$  and  $\text{Na}_2\text{SO}_4$  existing separately but as dissociated ionic components, and therefore it does not make a difference if one of skill in the art chooses  $\text{Na}(\text{NO}_3)_2$  and  $\text{CaSO}_4$  versus  $\text{Na}_2\text{SO}_4$  and  $\text{Ca}(\text{NO}_3)_2$ . This has been considered but not found persuasive. The ingredients listed in claim 1 are not listed as alternative ingredients but as a collective formula. It is further noted that the ranges for all the ingredients do not encompass zero for any ingredient. Further, the same argument applied to the above rejection for the need to optimize for every tumor type with regard to the medium formulation can be applied to the counter ions in solution as well as the ingredients used to formulate the solution, because one of skill in the art would be subjected

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to undue experimentation in order to make the medium useful for the propagation of primary tumor cells taken from patients.

All claims are rejected.

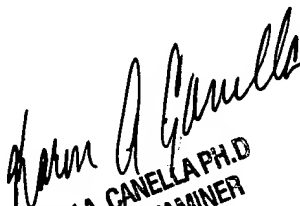
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

11/10/2006

  
KARENA. CANELLA PH.D.  
PRIMARY EXAMINER